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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/736,019	10/22/1996	ANDREW GOODEARL	04585/00200Q	3384
21559	7590	05/12/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			GUCKER, STEPHEN	
		ART UNIT		PAPER NUMBER
				1647

DATE MAILED: 05/12/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.



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KRISTINA BIEKER-BRADY, PH.D. CLARK & ELBING LLP 176 FEDERAL STREET BOSTON, MA 021102214			GUCKE, STEPHEN	
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Office Action Summary

Application No.	Applicant(s)	
08/736,019	GOODEARL ET AL.	
Examiner	Art Unit	
Stephen Gucker	1647	

**— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 132,136,137 and 139-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 132,136,137 and 139-142 is/are rejected.
- 7) Claim(s) 143 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Response to Amendment

1. The request filed on 5/23/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/736,019 is acceptable and a CPA has been established. An action on the CPA follows.
2. It is noted by the Examiner that the request for the CPA did not include a request for entry of the after-final amendment filed 7/29/02, so the Examiner has acted upon the claims as pending before 7/29/02. To help clarify the situation, the Examiner has included a copy of the pending claims as acted upon in this Office Action at the end of this action. Immediately following this copy of the pending claims is a version of the claims with markings to show changes made that the Examiner believed was Applicant's intention, had Applicant included a request to enter the after-final amendment filed 7/29/02 along with the request for the CPA.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
5. The Examiner would like to thank Applicant for the response to the previous request for information under 37 CFR 1.105. However, due to differing sequence listings in these patents and patent applications, the Examiner is forced to request further information.

Art Unit: 1647

6. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application:

7. Because of the large number of sequences and fragments of sequences presented for examination in the instant claims and in multiple co-pending and allowed applications, the Examiner is making a request for a listing and identification of all applications that Applicants have filed that claim the instant sequences either as discrete SEQ ID NOs or fragments of larger sequences in any methods of administration and/or treatment. The Examiner is making this request because the sequence listings in some of these applications exceeds 300 SEQ ID NOs, and the numbering scheme between applications has not always remained constant, such that a SEQ ID NO in one application may not correspond to the same SEQ ID NO in another application. In addition, the Examiner requests Applicants' assistance to provide a current update and identify which SEQ ID NOs correspond to which SEQ ID NOs currently being claimed in methods of use in the instant Application where the SEQ ID NOs are not identical. If fragments of larger sequences are being used or encoding nucleotide sequences, Applicants are requested to identify these sequences or subsequences by amino acid residue or nucleotide numbering. It is the Examiner's wish that with this update and identification, allowable subject matter in the instant Application can be more easily identified in relation to double-patenting issues, and these double-patenting issues resolved, so that the instant Application can proceed to allowance.

8. Claims 132, 136-137, and 139-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,204,241. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptides administered by the process steps recited in the instant application of *a method for inducing myelination of a neural cell by a glial cell* by using an amino acid sequence encoded by SEQ ID NO:154, or amino acid sequences comprising SEQ ID NO:188-189, or an amino acid sequence provided in SEQ ID NO:151, or amino acids 362-411 of SEQ ID NO:170, are polypeptides which are all contained within SEQ ID NO:170 of claim 11 of the instant patent which recites *a method for inducing myelination of a neural cell by a glial cell* comprising administering amino acids 51-422 of SEQ ID NO:170.

Furthermore, although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim recites the administration of a polypeptide (amino acids 51-422 of SEQ ID NO:170) and the instant claims recite the use of fragments of said polypeptide (SEQ ID NO:188 is residues 350-411 of SEQ ID NO:170, SEQ ID NO:189 is residues 350-422 of SEQ ID NO:170, SEQ ID NO:154 encodes a sequence found within SEQ ID NO:170, SEQ ID NO:151 is found within SEQ ID NO:170, and SEQ ID NO:170 is identical between the patent and the instant Application). The patented claim is a sub-genus of the instant claims because it recites a genus that is smaller than the instant genus, but completely encompassed by the claimed instant genus. Therefore, a species-genus relationship exists between the patented claim and the instant claims, and the patented claim renders the instant claims

obvious because the patented claim anticipates the instant claims and the patented species or sub-genus renders the instant genus claims obvious. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The grounds for this rejection could be obviated by having the after-final amendment filed 7/29/02 entered into the instant Application (most easily accomplished by re-submitting the amendment).

9. Claims 132, 136-137, and 139-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,635,249 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim recites the administration of a polypeptide (recombinant human GGF2) and the instant claims recite the use of fragments of said polypeptide (SEQ ID NO:188 is residues 350-411 of full-length recombinant human GGF2, SEQ ID NO:189 is residues 350-422 of full-length recombinant human GGF2, SEQ ID NO:154 encodes a sequence found within full-length recombinant human GGF2, and SEQ ID NO:151 is found within full-length recombinant human GGF2). The patented claim is a sub-genus of the instant claims because it recites a genus that is smaller than the instant genus, but completely encompassed by the claimed instant genus. Therefore, a species-genus relationship exists between the patented claim and the instant claims, and the patented claim renders the instant claims obvious because the patented claim anticipates the instant

claims and the patented species or sub-genus renders the instant genus claims obvious. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The grounds for this rejection could be obviated by having the after-final amendment filed 7/29/02 entered into the instant Application (most easily accomplished by re-submitting the amendment).

10. Claims 132, 136-137, and 139-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending U.S. Application No. 08/461,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claim recites the administration of a polypeptide (SEQ ID NO:324) and the instant claims recite the use of fragments of said polypeptide (SEQ ID NO:188 is residues 350-411 of SEQ ID NO:324, SEQ ID NO:189 is residues 350-422 of SEQ ID NO:324, SEQ ID NO:154 encodes a sequence found within SEQ ID NO:324, and SEQ ID NO:151 is found within SEQ ID NO:324). The co-pending claim is a sub-genus of the instant claims because it recites a genus that is smaller than the instant genus, but completely encompassed by the claimed instant genus. Therefore, a species-genus relationship exists between the patented claim and the instant claims, and the patented claim renders the instant claims obvious because the patented claim anticipates the instant claims and the patented species or sub-genus renders the instant genus claims obvious. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The grounds for this rejection could be obviated by having the after-final amendment filed 7/29/02 entered into the instant Application (most easily accomplished by re-submitting the amendment).

11. Claims 132, 136-137, and 139-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 145 of co-pending U.S. Application No. 08/471,833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptides administered by the process steps recited in the instant Application of a *method for inducing myelination of a neural cell by a glial cell* by using an amino acid sequence encoded by SEQ ID NOS:154-159, or an amino acid sequence provided in SEQ ID NOS:151-152, or an amino acid sequence encoded by nucleotides 161-310 of SEQ ID NO:150, are polypeptides which are identical to the polypeptides administered in the co-pending Application which recites a *method for inducing myelination of a neural cell by a glial cell*. The co-pending claim is a sub-genus of the instant claims because it recites a genus that is smaller (a method for treating multiple sclerosis) than the instant genus (a method for inducing myelination of a neural cell by a glial cell), but completely encompassed by the claimed instant genus. Therefore, a species-genus relationship exists between the co-pending claim and the instant claims, and the co-pending claim renders the instant claims obvious because the co-pending claim anticipates the instant claims and the co-pending species or sub-genus renders the instant genus claims

obvious. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The grounds for this rejection could NOT be obviated by having the after-final amendment filed 7/29/02 entered into the instant Application.

12. Claims 132 and 139-140 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of co-pending U.S. Application No. 09/530,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the polypeptides administered by the process steps recited in the instant Application of *a method for inducing myelination of a neural cell by a glial cell by using an amino acid sequence encoded by SEQ ID NO:158 or an amino acid sequence encoded by nucleotides 161-310 of SEQ ID NO:150*, are polypeptides which are fragments of the polypeptides administered in the co-pending Application which recites a method of treating a mammal suffering from or *susceptible to stroke, brain or spinal cord injury or ischemia, or heart attack, comprising administering to the mammal a therapeutically effective amount of a neuregulin, wherein the neuregulin is encoded by a nucleic acid that comprises one of SEQ ID NOS:49, 51, and 53*. SEQ ID NO:49 of the co-pending Application encodes within itself the amino acid sequence encoded by nucleotides 161-310 of SEQ ID NO:150 of the instant Application. SEQ ID NO:51 of the co-pending Application encodes within itself the amino acid sequence encoded by SEQ ID NO:158 of the instant Application. The co-pending claim is a sub-genus of the instant claims because it recites a genus that is

smaller (because the sequences used in the methods are larger sequences) than the instant genus (because the sequences used in the instant methods are encoded fragments of the larger sequences in the co-pending Application), but completely encompassed by the claimed instant genus. Therefore, a species-genus relationship exists between the co-pending claim and the instant claims, and the co-pending claim renders the instant claims obvious because the co-pending claim anticipates the instant claims and the co-pending species or sub-genus renders the instant genus claims obvious. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The grounds for this rejection could NOT be obviated by having the after-final amendment filed 7/29/02 entered into the instant Application.

13. Claim 143 is objected to as being dependent upon a rejected claim.
14. No claim is allowed.
15. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-

Art Unit: 1647

0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

April 14, 2004

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600